

Remarks

Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are pending in the subject application and read on the elected invention. Applicants acknowledge that claims 123, 125, 127, 128, 141-144, and 147-179 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, claims 115, 119, 148, and 152 have been amended. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1 and 115-179 (with claims 123, 125, 127, 128, 141-144, and 147-179 standing withdrawn) are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants thank the Examiner for issuing a new Office Action restarting the time period for response since the Action was mailed to the previous counsel of record on July 31, 2006. Applicants also thank the Examiner for his efforts in having the Revocation/New Power of Attorney documents (filed January 26, 2006) entered into this application.

Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are rejected under the judicially created doctrine of “obviousness-type” double patenting over claims 51-55 of U.S. Patent No. 6,965,033. The Office Action states that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because current claim 1 is drawn to a pharmaceutical composition comprising at least one insulin secretagogue and a FB Pase inhibitor selected from the group of formula I or IA, and '033 claim 51 is drawn to a method of treating diabetes comprising administering a compound of formula I (wherein formula I is equivalent to the compounds of currently claimed formula I and IA). As the '033 patent uses the open language ‘comprising’ additional antidiabetic compounds can be administered including sulfonylureas such as glyburide.” Applicants respectfully assert that the claims are not obvious over the cited patent and traverse the rejection.

A double patenting rejection of the obviousness-type is “analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103” except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 U.S.P.Q. 29 (C.C.P.A. 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re*

Braat, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985). Accordingly, the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection and the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966) are applied for establishing a background for determining obviousness under 35 U.S.C. 103, including the consideration of any indicia of non-obviousness, when making the obviousness-type double patenting analysis (emphasis added). Further, any obviousness-type double patenting rejection should make clear the differences between the inventions defined by the conflicting claims and the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claims of the pending application at issue would have been an obvious variation of the invention defined in a claim in the patent.

In the case of this rejection, it is respectfully submitted that the cited patent and the rationale utilized for establishing the rejection fail to establish that the claimed composition is obvious over the claims of the '033 patent. Rather, the Office Action simply states that "[A]s the '033 patent uses the open language "comprising"[,] additional antidiabetic compounds can be administered including sulfonylureas such as glyburide". Applicants respectfully submit that this simple assertion on the part of the Office Action fails to establish that the obviousness of the presently claimed invention over the claims cited in the '033 patent. The fact that the patent uses open language, such as comprising, does not necessarily render the present claims obvious.

Applicants also submit that the cited patent fails to teach or suggest each of the elements recited in the instant claims. As the Patent Office is aware, all the claim limitations must be taught or suggested by the prior art in order to establish the *prima facie* obviousness of a claimed invention, *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Each of the limitations of the instant claims is not taught or suggested by the reference; thus, it is respectfully submitted that the obviousness of the instant invention has not been established by the rejection of record. Finally, Applicants respectfully submit that current rejection of record fails to provide any teaching or suggestion that would have motivated one of ordinary skill in the art to formulate the claimed composition comprising a sulfonylurea, such as glyburide, and a compound of General Formula (I) or (IA). Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are rejected under the judicially created doctrine of “obviousness-type” double patenting over claim 1 of U.S. Patent No. 6,756,360. Applicants respectfully assert that the claims are not obvious over the cited patents. In this rejection, the Office Action argues that “[A]lthough the conflicting claims are not identical, they are not patentably distinct from each other because current claim 1 is drawn to a pharmaceutical composition comprising at least one insulin secretagogue and a FB Pase inhibitor selected from the group of formula I or IA, and '360 claim 1 is drawn to a pharmaceutical composition comprising an insulin sensitizer agent and an FB Pase inhibitor. In '360 claim 4 the FB Pase inhibitor is a compound selected from the formula I and IA wherein formula I and IA are identical to the formula I and IA of the current claim 1. Further glyburide is a known insulin sensitizer and secretagogue.” Applicants respectfully traverse the rejection.

The Office Action states that “glyburide is a known insulin sensitizer and secretagogue”; however, no evidence supporting such a statement is provided in the Office Action. Applicants respectfully submit that the instant application indicates that glyburide is an insulin secretagogue. Glyburide is not indicated to be an insulin sensitizer (see, for example, page 2, lines 15-20). As indicated above, the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of an obviousness determination. In the case of this rejection, there is no evidence supporting the Patent Office’s assertion that the glyburide is a known insulin sensitizer and secretagogue. Thus, it is respectfully submitted that the instant rejection has failed to establish that the claims of this application are unpatentable over the claims of the ‘360 patent and reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are rejected under 35 U.S.C. § 103(a) as obvious over Erion *et al.* (U.S. Patent No. 6,756,360) in view of Weber *et al.* (U.S. Patent No. 3,454,635). Claims 1, 115-122, 124, 126, 129-140, 145, and 146 are also rejected under 35 U.S.C. § 103(a) as obvious over Jiang *et al.* (U.S. Patent No. 6,965,033) in view of Weber *et al.* (U.S. Patent No. 3,454,635). The Office Action argues that the ‘033 patent and the ‘360 patent each teach the currently elected compound (Compound J) and its use for treating diabetes. The Office Action further argues that Weber *et al.* teach compositions comprising glyburide and their use in the treatment of diabetes. The Office Action then concludes that it would have been obvious to combine

glyburide with the claimed FB Pase inhibitors as each are useful in the treatment of diabetes (citing to *In re Kirkhoven*, 626 F.2d 846, 850 (C.C.P.A. 1980)). Applicants respectfully traverse.

While Applicants maintain that the obviousness-type double patenting rejections of record are not proper, Applicants also point out that the evidence of non-obviousness discussed herein with respect to the rejections set forth under 35 U.S.C. § 103(a) is also relevant to the double patenting rejections set forth in the Office Action. In the case of the instantly elected invention, Applicants respectfully submit that the combination of glyburide with the claimed FB Pase inhibitors, such as Compound J, demonstrates unexpectedly superior results when used in the treatment of diabetes as compared to the administration of either compound alone. In Example X, for example, the combination of Compound J and glyburide was assessed for pharmacologic activity in Zucker Diabetic Fatty rats (see pages 315-317). In this example, the combination treatment resulted in enhanced reduction in the area under the curve of blood glucose during the initial 4 hours post drug administration. Additionally, the combination treatment attenuated an increase in blood lactate levels that were observed in the compound J monotherapy group (see page 316, lines 30-31 and Figure 2 [page 317]). This result was more pronounced in chronic groups (page 317, lines 1-4). Further, Example Y indicates that the combination of glyburide and Compound J resulted in greater glucose lowering than either compound J or glyburide alone in chronic ZDF rats that were treated (see page 319). Applicants further submit that one skilled in the art would reasonably expect that compounds having core structures similar to those of Compound J (*e.g.*, such as those set forth in claims 115-132) would also be expected to demonstrate unexpectedly superior results as compared to individual monotherapy regimens. Thus, it is respectfully submitted that the claimed invention is not obvious in view of the cited combinations of references and reconsideration and withdrawal of the rejection is respectfully requested.

Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/gyl/sl